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9/30/99

**TERMINAL DISCLAIMER TO OBViate A PROVISIONAL DOUBLE
PATENTING REJECTION OVER A PENDING SECOND APPLICATION**

Attorney Docket No:
S1383/7002

In re Application of: Richard S. Blumberg et al.
Application No. 08/899,856
Filed: July 24, 1997
For: RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS

The owner*, The Brigham and Womens's Hospital, Inc. and Brandeis University, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending second Application Number 08/374,159, filed on January 17, 1995. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the second application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of any patent granted on the second application, as shortened by any terminal disclaimer filed prior to the parent grant, in the event that any such granted patent expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

1. Γ For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. [RE] The undersigned is an attorney of record.

September 29, 1999

Signature

Date

Edward R. Gates

Typed or Printed Name

* Certification under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP §324.

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SUBJECT: DECISION ON TERMINAL DISCLAIMER INFORMAL FORM

DATE: 9/30/99

TO EXAMINER: CUNNINGHAM

PARALEGAL TERRY Dey

APPL. S.N.: 81899854

ART UNIT: 1644

MAILROOM DATE 9/29/99

AFTER FINAL YES NO X NUMBER OF T.D(S). FILED 1

INSTRUCTIONS: I have reviewed the submitted T.D. with the results as set forth below. If you agree, please use the appropriate form paragraphs identified by this informal memo in your next office action to notify applicant about the T.D. If you disagree with my analysis or have questions at all about the acceptability of the T.D., please see me or our Special Program Examiner. THIS MEMO IS AN INFORMAL INTERNAL MEMO ONLY. IT MUST NOT BE MAILED TO APPLICANT, NOR SHOULD A COPY BE LEFT IN FILE.

The T.D. is PROPER and has been recorded. (See 14.23).

The T.D. is NOT PROPER and has not been accepted for the reason(s) checked below. (See 14.24).

The recording fee of \$_____ has not been submitted nor is there any pre authorization in the application file to charge to a deposit account. (See 14.26.07)

Application Examiner has not processed T.D. fee. (See fee authorization).

The T.D. does not satisfy Rule 321(b)(3) in that the person who has signed the T.D. has not stated his/her interest (and/or the extent of the interest of the business entity represented by the signature) in the application/patent. (See 14.26 and 14.26.01).

The T.D. lacks the enforceable only during the common ownership clause needed to overcome a double patenting rejection, Rule 321(c). (See 14.27, 14.27.01).

It is directed to a particular claims(s), which is not acceptable since "the disclaimer must be of a terminal portion of the term of the entire patent to be granted". MPEP 1490. (See 14.26, 14.26.02).

The person who signed the terminal disclaimer:

has failed to state his/her capacity to sign for the business entity. (See 14.28).

is not recognized as an officer of the assignee. (See 14.29 and possibly 14.29.01).

No documentary evidence of a chain of title from the original Inventor(s) to assignee has been submitted, nor is the reel and frame specified as to where such evidence is recorded in the office. 37 CFR 3.73(b). (See 1140 O.G. 72). NOTE: This documentary evidence or the specifying of the reel and frame may be found in the T.D. or in a separate paper submitted by applicant. (See 14.30).

No "statement" specifying that the evidentiary documents have been reviewed and that, to the best of the assignee's knowledge and belief the title is in the assignee seeking to take action. 37 CFR 3.73(b). (See 1140 O.G. 72) (See 14.31).

The T.D. is not signed. (See 14.26, 14.26.3). or 14.26.03 if TD is not signed by all the owners.

Attorney not of record in oath/decl. or a separate paper filed appointing a new or associate attorney. (See 14.29.01).

The serial number of the application (or the number of the patent) which forms the basis for the double patenting is missing or incorrect. (See 14.32).

The serial number of this application (or the number of the patent in reexam or reissue case(s) being disclaimed is missing or incorrect. (See 14.26, 14.26.04 or 14.26.05).

The period disclaimed is incorrect or not specified. (See 14.27, 14.27.2 or 14.27.3) (For Samples 14.27.04 and 14.27.05)

Other: _____

Suggestion to request refund of \$_____. (See 14.35, 14.36).

EXAMINER NOTE: IF APPLICATION IS IN CONDITION FOR ALLOWANCE ANY OF THE ABOVE INFORMALITIES MAY BE FAXED IN TO THE GROUP

FOR SAMPLE TERMINAL DISCLAIMERS AND CERTIFICATES:

Sample of a TD over a pending application and assignee Certificate (See 14.37).

Sample of a TD over a prior patent and assignee Certificate (See 14.38).

Sample Assignee Certificate under 37 CFR 3.73 (b) (See 14.39)